DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 13, 2015

SpineFrontier, Incorporated
% Ms. Meredith May
Senior Manager
Empirical Consulting
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K142504
Trade/Device Name: SpineFrontier Lumbar Interbody Fusion Device System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 15, 2015
Received: April 16, 2015

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142504

Device Name
SpineFrontier Lumbar lnterbody Fusion Device System

Indications for Use *(Describe)*

The SpineFrontier Lumbar Interbody Fusion Device System (Dorado IBC, Dorado PLIFT, Dorado ELIFT, Arena-L, Dorado TILT, Dorado TLIFT, Dorado Wide, and Ursa S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The SpineFrontier Lumbar Intervertebral Body Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FORM FDA 3881 (9/13)

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5. 510(K) SUMMARY

Submitter's Name:	SpineFrontier
Submitter's Address:	500 Cummings Center, Suite 3500 Beverly, MA 01915
Submitter's Telephone:	978.232.3990 x252
Company Contact Person:	Manthan Damani, MSRA Sr. Regulatory Affairs Associate
Official Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	15-Apr-15
Trade or Proprietary Name:	SpineFrontier Lumbar lnterbody Fusion Device System
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification:	Class II per 21 CFR §888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices Orthopaedic and Rehabilitation Panel

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SpineFrontier Ti-Coated Lumbar Interbody Fusion Device System is a spinal intervertebral body fusion device system intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The system is comprised of devices made of titanium coated PEEK Optima® LT1, with varying widths, lengths, and heights to fit the anatomical needs of patients. The devices have raised contours on the superior and inferior surfaces that will resist device movement following implant.

The purpose of this submission is the addition of a CP-Ti coating on a previously cleared lumbar intervertebral fusion device.

INDICATIONS FOR USE

The SpineFrontier Lumbar Interbody Fusion Device System (Dorado IBC, Dorado PLIFT, Dorado ELIFT, Arena-L, Dorado TILT, Dorado TLIFT, Dorado Wide, and Ursa S-LIFT) is intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and

have had six months of non-operative treatment.

The SpineFrontier Lumbar Intervertebral Body Fusion Device System is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine.

TECHNOLOGICAL CHARACTERISTICS

Lumbar Interbody Fusion Device System is made from PEEK Optima® LT1 with Titanium Coating. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism
- Principles of operation

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Type**
K111553	Lumbar Interbody Fusion Device System	SpineFrontier	Primary
K071724, K110632	Lucent PLIF System	Spinal Element	Reference
K130573	Interbody System	Tyber Medical	Reference

PERFORMANCE DATA

The SpineFrontier Lumbar Interbody Fusion Device System has been tested and its coating characterized in the following test modes:

- Static axial compression per ASTM F2077
- Static compressive shear per ASTM F2077
- Static torsion per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Dynamic compressive shear per ASTM F2077
- Percent Porosity per ASTM F1854-09
- Coating Thickness per ASTM F1854-09
- Static Shear per ASTM F1044-05
- Static Tensile per ASTM F1147-05
- Shear Fatigue per ASTM F1160-05
- Abrasion per ASTM F1978-00

The results of this non-clinical testing show that the strength of the Lumbar Interbody Fusion Device System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the SpineFrontier Lumbar Interbody Fusion Device System is substantially equivalent to the predicate device.